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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,465	10/19/2000	Peter Kufer	147-199P	3425
2292	7590	07/08/2005	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			CHEU, CHANGHWA J	
		ART UNIT		PAPER NUMBER
		1641		

DATE MAILED: 07/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/554,465	KUFER ET AL.
	Examiner	Art Unit
	Jacob Cheu	1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 25 April 2005.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-35 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-8, 10, 11 and 19-21 is/are rejected.
- 7) Claim(s) 9, 12-18 and 22-35 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.



### **DETAILED ACTION**

Applicant's amendment filed on 4/25/2005 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 34-35 are added to the instant application.
2. Claims 1-35 are under examination.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With respect to claim 1, step (a), line 5, "an anchoring domain" is vague and confusing. It is not clear where this domain is located.

With respect to claim 1, step (a), line 5, "an anchoring domain" is vague and confusing. It is not clear whether this "anchoring domain" is the second domain.

With respect to claim 2, line 6, "said additional domain" is vague and confusing. It is not clear whether this "additional domain" is the third or second domain.

With respect to claim 30, line 4, "figure 6.10." does not comply with sequence rule. Applicant needs to clarify and recite SEQ ID No.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-8, 10-11, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holliger et al. (US 5837242).

Holliger et al. teach a composition for identifying binding antigens. Holliger et al. teach that the composition comprises two domains, where one domain is a binding domain which positioned C-terminal to a second domain, and the two domains are expressed in a biological display system, e.g. phage library, to identify predetermined epitope of interest (See Figure 9G, particularly both domains are linked by a linker; Col. 15, line 5-29). However, Holliger et al. do not explicitly teach coupling with an additional anchoring domain protein for attaching to the surface of the display phage system.

Barbas et al. teach using the C-terminal domain of the gene III protein in display library assay, e.g. mediating anchoring, to increase the sensitivity, e.g. 103- 105 fold (See

Abstract, Table I). Therefore, it would have been obvious at the time the invention was made to have motivated artisan in the art as Holliger et al. to incorporate the C-terminal domain of the gene III in the display library as taught by Barbas et al. to increase sensitivity and efficiency of the phage display system for identifying binding antigen.

With respect to claim 2, Holliger et al. teach using a polypeptide linker to couple the two domains (See Figure 9G).

With respect to claim 3, Holliger et al. teach the binding site domain is a pair of VH-VL (See Figure 9).

With respect to claim 6, Holliger et al. teach making the antibody pair (See example 1-3).

With respect to claim 8, the domain comprises more than 9 amino acid (See Example 1-3).

#### ***Response to Applicant's Arguments***

Applicant's arguments with respect to claims 1-33 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Patentably Distinct Invention***

Applicant's arguments that elected SED ID No. 75 from scFv fragment CDR region is not a patentably distinct invention with respect to the other recited SEQ ID No. 61, 63, 65, 67, 69, 71, 73 and 77. Applicant's arguments have been considered and are persuasive. Accordingly, the rest of the recited SEQ ID are joined for examination.

#### ***Allowable Subject Matter***

6. Claims 9, 12-18, 22-35 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: no prior art teaches or fairly suggests coupling a N2-domain of the gene III of the phage to the binding domain comprising with heavy chain/light chain or heavy/heavy or light/light chain. The prior art of Rudert et al. (US 6667150) merely teaches the N1-N2 domain or N1 domain, but not N2 alone involving increasing infection efficiency (emphasis added). Furthermore, no specific SEQ ID No.61, 63, 65, 67, 69, 71, 73, 75 and 77 as the CDR region has been taught or suggested in the art.

***Conclusion***

7. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period; then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu   
Examiner

Art Unit 1641

June 28, 2005

  
LONG V. LE  
SUPERVISORY PATENT EXAMINER  
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07/06/05